Food and Drug Administration

DCIS REPORT EVALUATION

October 23, 1997 Rev. 1

The following form is <u>For Your Information Only</u>. The form was drafted and is being utilized by FDA's Design Control Inspectional Strategy Team to evaluate completed Design Control Inspectional Strategy Reports. Every completed Design Control Inspectional Strategy Report will be evaluated using this form so that information may be compiled on the transition year for the design control requirements. The information collected will in part be utilized to make presentations at the Design Control Open Public Meeting being scheduled for January/February 1998.

This first year (June 1, 1997 - May 31, 1998) is a learning year in regards to design controls for both FDA and industry. The evaluation or auditing of completed DCIS reports is done as part of the learning process and recognizes that both FDA and industry personnel are learning the design control requirements through experience.

Please contact the Design Control Inspectional Strategy Team Leader (Kim Trautman, HFZ-340, 301-594-4648) to discuss any questions, comments or concerns regarding this evaluation.

Case #

1. Was cover sheet submitted with the DCIS Report? Yes ☐ No ☐
   Comments:

2. Was correct Design Control PAC used? CD ☐ Yes ☐ No ☐
   Comments:

82830D GMP Domestic
83830D Pre/Post Domestic
82R915 GMP Foreign
83R915 Pre/Post Foreign

3. Was DCIS report signed and dated by the investigator? Yes ☐ No ☐
   Comments:

4. If no design project was available for review, were the general design control procedures evaluated and DCIS report completed? N/A ☐ Yes ☐ No ☐
   Comments:

5. Does the DCIS report adequately describe the selected device? N/A ☐ Yes ☐ No ☐
   Comments:

6. a) Is the device selected for review subject to design controls? Yes ☐ No ☐

   b) If not, does the DCIS report clearly explain why selection of the device was appropriate? Yes ☐ No ☐
   Comments:

7. a) Were records prior to 6/1/97 audited? CD ☐ Yes ☐ No ☐

   b) If yes, did the firm request the audit and consent to the record review? CD ☐ Yes ☐ No ☐
   Comments:

8. a) Were any documents other than the overall design control procedure collected? Yes ☐ No ☐

   b) If yes, was collection of the other documents justified? CD ☐ Yes ☐ No ☐
   Comments:

9. a) Do the responses indicate that the investigator/manufacturer misunderstood some of the requirements of the regulation? CD ☐ Yes ☐ No ☐
   Investigator ☐ Manufacturer ☐

   b) If yes, which sections of the regulation? 820.30
   a ☐ b ☐ c ☐ d ☐ e ☐ f ☐ g ☐ h ☐ i ☐ j ☐
   Comments:

10. a) Were adequate (complete, responsive and sufficiently detailed) responses to the DCIS report questions provided? Yes ☐ No ☐

    b) If not, provide section/question number corresponding to inadequate responses, and any reviewer's comments:
    Comments:

AREAS OF NEEDED IMPROVEMENT:

11. a) Were there any Areas of Needed Improvement documented? Yes ☐ No ☐
    If no, skip to question 12.

b) Are any of the listed Areas of Needed Improvements not deviations from 21 CFR 820.30? Yes ☐ No ☐
If yes, identify the item number(s).
Comments:

c) Are each of the listed Areas of Needed Improvement explained/supported by responses in DCIS Report? Yes ☐ No ☐
If not, identify the item number(s).
Comments:

d) Do discussions of Areas of Needed Improvements identify the supporting documents that were reviewed? Yes ☐ No ☐
If not, specify the item number(s).
Comments:

e) Do the Areas of Needed Improvement include inappropriate evaluations of safety, efficacy, product specifications or risk analysis/mitigation? Yes ☐ No ☐
If yes, specify the item number(s).
Comments:

f) Are Areas of Needed Improvement succinct, direct, clearly understandable, significant and not redundant? Yes ☐ No ☐
If no, specify the item number(s).
Comments:

12. Do Areas of Needed Improvement capture all significant nonconformances identified in the narrative? Yes ☐ No ☐
If no, identify the narrative section/question.
Comments:

13. Does DCIS report address the following when appropriate?

a) Human Factors N/A ☐ Yes ☐ No ☐

b) EMC/EMI N/A ☐ Yes ☐ No ☐
Comments:

14. In discussions of design validation, are process validation issues inappropriately discussed or confused with design validation? Yes ☐ No ☐
    Comments:

RISK ANALYSIS:

15. a) Was risk analysis conducted? CD ☐ Yes ☐ No ☐

    b) At what stage(s) in the design process is risk analysis conducted?
    Comments:

    c) Did the firm document justification for not conducting risk analysis? N/A ☐ Yes ☐ No ☐

    d) What tools and techniques were used to conduct risk analysis?
    FMEA ☐ FMECA ☐ FTA ☐ In-House ☐ Other ☐
    Comments:

16. Overall Assessment:
    Comments